REMARKS

Claims 1-44 were pending prior to this response. By the present communication, no claims have been added and claims 9, 13-14, and 19 have been amended. Claims 1, 5, 6, 8, 11, 12, 18 and 20-44 have been withdrawn from consideration. Thus, upon entry of the present communication, claims 2-4, 7, 9-10, 13-17, and 19 will be pending in this application.

Rejections under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 14-17 as allegedly failing to comply with the enablement requirement of 35 U.S.C. §112, first paragraph. The Examiner alleges that claims 14-17 contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make or use the invention.

The test for enablement is whether the specification contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention (see MPEP §2164.01). Additionally, the claims of the present application should be read in the context of the specification in which they arise and in which the invention is described (see Galverbel Societe Anomyme v. Northlake Marketing & Supply, Inc., 33 USPQ 2d 1496 (Fed. Cir. 1995)).

The Examiner alleges that one skilled in the art would not easily recognize all compounds that are capable of binding GTRAP3-18 as glycosylation modulators. Applicants respectfully disagree and submit that the specification clearly teaches that GTRAP3-18 is a modulator of cellular glycosylation (see for example, page 60 of the specification and Figures 6A and 6B). Since GTRAP3-18 is a modulator of cellular glycosylation, a compound that binds GTRAP3-18 may alter the glycosylation activity of GTRAP3-18. Additionally, Applicants submit that where a compound binds GTRAP3-18 and is not a glycosylation modulator, 35 U.S.C. §112, first paragraph, does not require every claimed embodiment be operable (see Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 224 USPQ 409 (Fed. Cir. 1984)). Furthermore, the specification clearly teaches various

screening assays to identify compounds which modulate GTRAP3-18 expression, GTRAP3-18 activity, and cellular glycosylation (see for example, pages 13-15 of the specification).

Further, the Examiner alleges that the quantity of experimentation required to develop GTRAP3-18 binding proteins as effective treatments for disease would be undue in the absence of any direction or guidance from the specification. Applicants respectfully disagree for the following reasons. Applicants submit that the specification provides direction and guidance to enable one skilled in the art to develop GTRAP3-18 binding proteins as treatments for disease. See, for example, the specification at page 11 which discloses a listing of disorders marked by misregulation of GTRAP3-18 activity. It would be routine for one skilled in the art to test a compound that binds GTRAP3-18 as a treatment for one of the disclosed diseases. The fact that experimentation may be complex does not necessarily make it undue (see Massachusetts Institute of Technology v. A.B. Fortia, 227 USPQ 428 (Fed. Cir. 1985)).

Further, the Examiner asserts that the specification allegedly does not include a working example showing successful treatment of any disease and therefore the claims lack enablement. Applicants respectfully disagree and submit that the absence of a working example does not render an invention non-enabled (see MPEP §2164.02). Applicants respectfully submit that the specification provides ample teachings to allow one skilled in the art to treat glycosylation associated disorders using compounds identified by the present invention. See, for example, the specification at pages 29-37 which teaches various therapeutic methods for treating a subject suffering from a glycosylation associated disorder.

Accordingly, Applicants respectfully submit that the claims are enabled because the specification provides appropriate guidance and direction to enable one skilled in the art to make and use the claimed invention in the absence of undue experimentation. For the aforementioned reasons, Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C §102

The Examiner asserts that claims 2, 4, 7, 9, 13, 14-16 are rejected under 35 U.S.C. §102(a), as allegedly being anticipated by Butchbach et al. (*Journal of Neurochemistry*, 84: 891-894 (Feb. 15 2003)), as evidenced by Saez-Valero et al. (*Journal of Neurology, Neurosurgery and Psychiatry*, 69: 664-667, (2000)) and Fassbender et al. (*Proc. Natl. Acad. Sci. U.S.A.*, 98, 5856-5861 (2001)). Applicants respectfully traverse the rejection of claims 2, 4, 7, 9, 13, 14-16, and 19 under 35 U.S.C. §102(a) as allegedly being anticipated by Butchbach et al. for the reasons given below.

The Office Action alleges, in pertinent part, that the cited reference Butchbach et al. teaches the elements as recited in the present claims. Specifically, the Examiner asserts that Butchbach et al. allegedly teaches the identification of compounds (methyl-β-cyclodextrin and retinoic acid) which when applied to neuronal cells (rat neuron cultures) modulates GTRAP3-18 protein expression and activity. Furthermore, the Examiner asserts that Saez-Valero et al. allegedly identifies Alzheimer's disease as a glycosylation associated disorder and Fassenbender et al. allegedly teaches that the compound methyl-β-cyclodextrin of the Butchbach et al. reference is capable of treating Alzheimer's disease by lowering toxic amyloid products.

Under 35 U.S.C. §102(a), a person is entitled to a patent unless the invention was described in a printed publication before the invention thereof by the Applicant. Applicants note that the Examiner has acknowledged Applicants' claim of priority to the earlier filed provisional application 60/440,717, filed January 17, 2003. Applicants respectfully submit that Applicants effective priority date of January 17, 2003, antedates the publication date of Butchbach et al. of February 15, 2003 and thus the invention was not described in a printed publication before the invention thereof by the Applicant. Accordingly, Applicants request the rejection be withdrawn in light of Applicants' earlier filed provisional application.

Furthermore, under 35 U.S.C. §102, a reference anticipates only if the reference teaches each and every element of the claimed invention. Claim 1 expressly recites the limitation "wherein a compound that can modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide

or the activity of a GTRAP3-18 polypeptide is identified as a compound capable of modulating cellular glycosylation." Both Saez-Valero et al. and Fassenbender et al. fail to teach either 1) the correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation, or 2) the identification of such a modulator.

Failure of the cited references Saez-Valero et al. and Fassenbender et al. to meet every element of the claimed invention does not meet the standard under 102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

The Examiner asserts that claims 2, 4, 7, 9-10, and 13 are rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Lin et al. (*Nature*, 410: 84-88 (March 1, 2001)). Applicants respectfully traverse the rejection of claims 2, 4, 7, 9-10, and 13 under 35 U.S.C. §102(b) as allegedly being anticipated by Lin et al. for the reasons given below.

The Office Action alleges, in pertinent part, that the cited reference Lin et al. teaches the elements as recited in the present claims. Applicants respectfully disagree and submit that Lin et al. fails to teach each and every element of the claimed invention. Under 35 U.S.C. §102, a reference anticipates only if the reference teaches each and every element of the claimed invention. Claim 1 expressly recites the limitation "wherein a compound that can modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide or the activity of a GTRAP3-18 polypeptide is identified as a compound capable of modulating cellular glycosylation." Lin et al. fails to teach either 1) the correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation, or 2) the identification of such a modulator.

Failure of the cited reference Lin et al. to meet every element of the claimed invention does not meet the standard under 102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

The Examiner asserts that claims 2, 4, 7, 9, 13 and 19 are rejected under 35 U.S.C. §102(e), as allegedly being anticipated by US Patent No. 6,808,893. Applicants respectfully traverse the

rejection of claims 2, 4, 7, 9, 13 and 19 under 35 U.S.C. §102(e) as allegedly being anticipated by US Patent No. 6,808,893 for the reasons given below.

The Office Action alleges, in pertinent part, that the cited reference US Patent No. 6,808,893 teaches the elements as recited in the present claims. Applicants respectfully disagree and submit that US Patent No. 6,808,893 fails to teach each and every element of the claimed invention. Under 35 U.S.C. §102, a reference anticipates only if the reference teaches each and every element of the claimed invention. Claim 1 expressly recites the limitation "wherein a compound that can modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide or the activity of a GTRAP3-18 polypeptide is identified as a compound capable of modulating cellular glycosylation." US Patent No. 6,808,893 fails to teach either 1) the correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation, or 2) the identification of such a modulator.

Failure of the cited reference US Patent No. 6,808,893 to meet every element of the claimed invention does not meet the standard under 102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C §103(a)

Applicants respectfully traverse the rejection of claims 3 and 13 under 35 U.S.C. §103(a), as allegedly being unpatentable over Lin et al. as applied to claims 2, 4, 7, 9-10 and 13, and further in view of Hirabayashi and Kasai (*Journal of Chromatography B*, 771: 67-87 (May 5, 2002)). The recent U.S. Supreme Court decision in the KSR International v. Teleflex Inc. (82 USPQ 2d 1385), modified the standard for establishing a *prima facie* case of obviousness. Under the KSR rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references.

The Examiner alleges that Lin et al. teaches antisense oligomer and retinoic acid modulation of GTRAP3-18 protein expression and activity as determined by glutamate transport via coexpressed EAAC1. However, Lin et al. does not teach or suggest all of the recited claim limitations of the present invention. For example, Lin et al. fails to teach or suggest the limitation of claim 1, which recites "wherein a compound that can modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide or the activity of a GTRAP3-18 polypeptide is identified as a compound capable of modulating cellular glycosylation." Applicants submit that Lin et al. is absolutely silent with regard to identification of compounds that modulate the expression or activity of GTRAP3-18 as compounds capable of modulating cellular glycosylation.

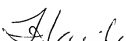
Accordingly, even if one were to combine Lin et al. with Hirabayashi et al., the resulting combination would not be *prima facie* obvious over the claimed invention since the combined references do not disclose each and every claim limitation. Thus, since Applicants identified and claimed the unexpected result of identifying compounds that modulate the expression or activity of GTRAP3-18 as compounds capable of modulating cellular glycosylation, Applicants submit that a *prima facie* case of obviousness has not been established. Applicants respectfully request withdrawal of the rejection.

Conclusion

In summary, for the reasons set forth herein, Applicants submit that the claims clearly and patentably define the invention and respectfully request that the Examiner withdraw all rejections and pass the application to allowance. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

The Commissioner is hereby authorized to charge the total amount of $705.00 as payment for the Three-Month Extension of Time fee ($525.00, small entity) and Information Disclosure Statement ($180.00) to Deposit Account No.: 07-1896. No other fee is deemed necessary with this filing, however, the Commissioner is also authorized to charge any additional fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,



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